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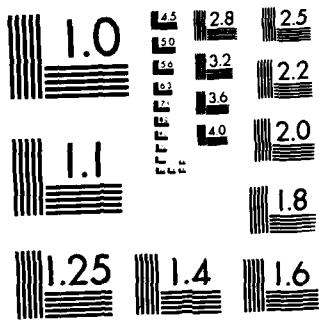
TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT
REPELLENT AI3-78948. (U) ARMY ENVIRONMENTAL HYGIENE
AGENCY ABERDEEN PROVING GROUND MD J V MADE 25 JUL 84
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UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY

ABERDEEN PROVING GROUND, MD 21010-5422

TOPICAL HAZARD EVALUATION PROGRAM
OF

CANDIDATE INSECT REPELLENT
AI3-70948-Ga

US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL
STUDY NO. 75-51-0466-84
DECEMBER 1983 - MARCH 1984

JUL 27 84

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Chemical AI3-70948 Ga produced no primary skin irritation. It produced moderate injury to the cornea and, in addition, some injury to the conjunctiva upon application to the eyes of rabbits. Ocular injury was unresolved at 7 days post-application in three of the nine rabbits tested and included scarring and constriction of the eyelids. This chemical was relatively nontoxic upon ingestion. Recommend that chemical AI3-70948-Ga be disapproved for further testing as a candidate insect repellent due to its potential to produce severe, permanent ocular injury.		



DEPARTMENT OF THE ARMY CPT(P) Wade/cvc/AUTOVON
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY 584-3627
ABERDEEN PROVING GROUND, MARYLAND 21010-5422

REPLY TO
ATTENTION OF

HSHB-OT/WP

25 JUL 1984

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent
AI3-70948-Ga, US Department of Agriculture Proprietary Chemical,
Study No. 75-51-0466-84, December 1983 - March 1984

Executive Secretary
Armed Forces Pest Management Board
Forest Glen Section, WRAMC
Washington, DC 20307

EXECUTIVE SUMMARY

The purpose, essential findings, and major recommendations of the inclosed report follow:

a. Purpose. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-70948-Ga by means of laboratory animal studies using New Zealand White rabbits and Sprague-Dawley rats.

b. Essential Findings. Chemical AI3-70948-Ga produced no primary skin irritation. It produced moderate injury to the cornea and, in addition, some injury to the conjunctiva upon application to the eyes of rabbits. Ocular injury was unresolved at 7 days postapplication in three of the nine rabbits tested and included scarring and constriction of the eyelids. This chemical was relatively nontoxic upon ingestion.

c. Major Recommendations. Recommend that chemical AI3-70948-Ga be disapproved for further testing as a candidate insect repellent.

FOR THE COMMANDER:

JOEL C. GAYDOS, M.D.
Colonel, MC
Director, Occupational and
Environmental Health

1 Incl
as (5 cy)

CF:
HQDA (DASG-PSP) wo incl
Cdr, HSC (HSCL-P)
Comdt, AHS (HSMA-IPM)
Dir, Advisory Cen on Tox, NRC (2 cy)
USDA, ARS (Dr. Terrence McGovern)
USDA, ARS, Southern Region (3 cy)
Cdr, USAMRDC [SGRD-DPM/LTC(P) Reinert]



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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010-5422

REPLY TO
ATTENTION OF

HSHB-OT/WP

TOPICAL HAZARD EVALUATION PROGRAM
OF
CANDIDATE INSECT REPELLENT AI3-70948-Ga
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL
STUDY NO. 75-51-0466-84
DECEMBER 1983 - MARCH 1984

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research, Southern Region, Insects Affecting Man and Animals Research Laboratory, Gainesville, Florida, 1 December 1983.

b. Memorandum of Understanding between the US Army Environmental Hygiene Agency; the US Army Health Services Command; the Department of the Army, Office of The Surgeon General; the Armed Forces Pest Control Board; and the US Department of Agriculture, Agricultural Research, Science and Education Administrations; titled Coordination of Biological and Toxicological Testing of Pesticides, effective 23 January 1979.

2. REFERENCE. Toxicology Division Topical Hazard Evaluation Program Procedural Guide, US Army Environmental Hygiene Agency (USAEEHA), January 1982.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-70948-Ga, US Department of Agriculture (USDA) Proprietary Chemical.

4. SUMMARY OF FINDINGS. Hazard evaluations of the candidate insect repellent AI3-70948-Ga, USDA Proprietary Chemical, were conducted by this Agency using New Zealand White rabbits and Sprague-Dawley rats. A tabular presentation of animal toxicity data developed by this Agency follows:^{*†}

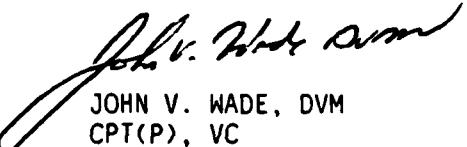
* In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals"; US Department of Health, Education, and Welfare; Public Health Service; National Institutes of Health (NIH) Publication No. 80-23, revised 1978, reprinted April 1980.

† The studies reported herein were performed in animal facilities fully accredited by the American Association for the Accreditation of Laboratory Animal Care.

Study No. 75-51-0466-84, Dec 83 - Mar 84

5. CONCLUSION. Chemical AI3-70948-Ga produced no primary skin irritation. It produced moderate injury to the cornea and, in addition, some injury to the conjunctiva upon application to the eyes of rabbits. Ocular injury was unresolved at 7 days postapplication in three of the nine rabbits tested and included scarring and constriction of the eyelids. This chemical was relatively nontoxic upon ingestion. These studies were monitored by Analytical Quality Assurance Office (see Appendix B).

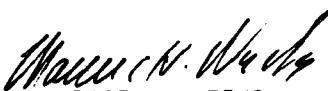
6. RECOMMENDATION. Recommend that chemical AI3-70948-Ga be disapproved for further testing as a candidate insect repellent due to its potential to produce severe, permanent ocular injury.



John V. Wade, DVM

CPT(P), VC
Laboratory Animal
Veterinary Officer
Toxicology Division

APPROVED:



MAURICE H. WEEKS
Chief, Toxicology Division

APPENDIX A

TOPICAL HAZARD EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING
CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesication, and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals, prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

EYE CATEGORIES:

A. Compounds noninjurious to the eye. INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.

B. Compounds producing mild injury to the cornea. INTERPRETATION: Should be used with caution around the eyes.

C. Compounds producing mild injury to the cornea, and in addition some injury to the conjunctiva. INTERPRETATION: Should be used with caution around the eyes and mucosa.

D. Compounds producing moderate injury to the cornea. INTERPRETATION: Should be used with extreme caution around the eyes.

E. Compounds producing moderate injury to the cornea, and in addition producing some injury to the conjunctiva. INTERPRETATION: Should be used with extreme caution around the eyes and mucosa.

F. Compounds producing severe injury to the cornea and to the conjunctiva. INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face.

APPENDIX B

ANALYTICAL QUALITY ASSURANCE

The Analytical Quality Assurance Office certifies the following:

a. These studies were conducted in accordance with:

(1) Standing Operating Procedures developed by the Toxicology Division, USAEHA.

(2) Title 21, Code of Federal Regulations (CFR), 1983 rev, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

(3) Final Rule, Pesticide Programs; Good Laboratory Practice Standards; 48 Federal Register (FR) 53946-53969, 29 November 1983.

(4) Final Rule, Toxic Substances Control; Good Laboratory Practice Standards; 48 Federal Register (FR) 53922-53944, 29 November 1983.

b. Facilities were inspected during its operational phase to ensure compliance with paragraph a above.

c. The information presented in this report accurately reflects the raw data generated during the course of conducting these studies.


PAUL V. SNEERINGER, Ph.D.
Chief, Analytical Quality
Assurance Office

